

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460



Office of Pesticide Programs

MEMORANDUM

5/15/2017

SUBJECT: Acute Toxicity Review for Arnie, EPA Reg. No.: 3573-RNR
DP 439676

FROM: Chemistry and Acute Toxicology Science Advisory Council (CATSAC)
Co-Chair: Karen Hicks

Reviewer: Ian Blackwell
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

THRU: Jenny Tao, Senior Scientist
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

TO: Eric Miederhoff, PM Team 31 / Joseph Daniels
Regulatory Management Branch I
Antimicrobials Division (7510P)

Registrant: The Procter and Gamble Company		
Decision No.: 523660	Submission No.: 995676	E-Sub No.: n/a
MRID No(s): None		

Formulation from label			
PC code(s)	CAS #(s)	Active Ingredient(s)	% weight
069149	7173-51-5	Didecyl dimethyl ammonium chloride	1.65
		Other Ingredients	98.35
		Total	100%

- I BACKGROUND: The Procter & Gamble Company (P&G) has submitted three acute toxicity studies for acute oral toxicity (MRID 50107407), acute dermal toxicity (MRID 50107408), and primary skin irritation (MRID 50107410) and waiver requests in support of the registration of their product, *Arnie*, EPA Reg. No. 3573-RNR. The submitted label describes this product as a soft surface (fabric) sanitizer, deodorizer and fungistat.

The registrant has requested a waiver of the acute inhalation toxicity study (MRID 50107409) based on the following:

1. *Arnie* is to be sold only for use with an automatic closed-loop delivery system. When used as designed, this system is thought to prevent exposure to the concentrated version of this product.
2. The plug in the bottle is a one-way valve and is only available when the dispensing cap is attached to the bottle.
3. The closed-loop system dilutes 3573-RNR five times prior to its delivery of the product.

The Chemistry and Toxicology Team conducted an acute toxicology review of EPA File Symbol 3573-RNR (concentrate) on 2/24/2017. CTT rejected the acute inhalation toxicity study waiver in that review. The registrant responded to that review with an additional rationale for the acute inhalation toxicity waiver. CTT took this submission to the Chemistry and Acute Toxicology Science Advisory Council (CATSAC) for a formal evaluation. This memo provides the CATSAC decision and the CTT acute toxicity review for the proposed product, *Arnie*, EPA Reg. No. 3573-RNR.

II DECISION:

1. The acute oral and dermal toxicity studies are acceptable.
2. The Chemistry and Acute Toxicology Science Advisory Council (CATSAC) has decided that due to the low concentration of active ingredient, the low volatility of the active ingredient itself and guidance found in the 2/9/2015 Product Reregistration Batching Guidance for Quaternary Ammonium Compounds (Cases 0350 and 3003) - Acute Mammalian Toxicity Data Requirements that discussed inhalation classification, a waiver of the acute inhalation toxicity study would be granted and the product assigned a toxicity category III.
3. CTT waives the primary eye irritation study and classifies the product toxicity category I due to the percentage of DDAC in this product. In the future, if the registrant develops new data demonstrating that this product should be assigned a toxicity category other than I, CTT will take it into consideration.
4. The primary skin irritation study is acceptable.

5. CTT waives the dermal sensitization study and classifies the product as a sensitizer. The registrant previously requested a waiver to classify this product as a sensitizer in a 2/24/2017 review of 3573-RNR due to the product's formulation.

The acute toxicity profile for File Symbol 3573-RNR (concentrated) is currently:

Study	MRID Number	Toxicity Category	Study Status
Acute Oral Toxicity	50107407	IV	Acceptable
Acute Dermal Toxicity	50107408	III	Acceptable
Acute Inhalation Toxicity	50107409	III	Waived
Primary Eye Irritation	50107406	I	Waived
Primary Skin Irritation	50107410	III	Acceptable
Dermal Sensitization	50107406	Sensitizer	Waived

III LABELING:

Label Review System

PRODUCT ID #: 003573-00101

PRODUCT NAME: Arnie

PRECAUTIONARY STATEMENTS

SIGNAL WORD: DANGER

Hazards to Humans and Domestic Animals:

Restricted Use Pesticide due to toxicity categories. For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification. Child Resistant Packaging Required.

Corrosive. Causes irreversible eye damage. Harmful if inhaled or absorbed through skin. Avoid contact with skin or clothing. Do not get in eyes or on clothing. Avoid breathing spray mist. Avoid contact with skin. Wear protective eyewear (goggles, face shield, or safety glasses). Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove and wash contaminated clothing before reuse. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

First Aid:

If in eyes:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
- Call a poison control center or doctor for treatment advice.

If on skin:

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or doctor for treatment advice.

If inhaled:

- Move the person to fresh air.
- If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible.
- Call a poison control center or doctor for further treatment advice.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

Note to PM/CRM/Registrant: The proposed label should contain a Note to Physician which addresses the category I Primary Eye Irritant toxicity. The following statements are suggested types of information that may be included, if applicable:

- technical information on symptomatology;
- use of supportive treatments to maintain life functions;
- medicine that will counteract the specific physiological effects of the pesticide;
- company telephone number to specific medical personnel who can provide specialized medical advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. For general information on product use, etc., call the National Pesticides Information Center at 1-800-858-7378. You may also contact the poison control center at 1-800-222-1222 for emergency medical treatment information.

Label Created by: Ian Blackwell on 05/03/2017 Last Updated by: Ian Blackwell on 05/03/2017

The Precautionary Statements for the 1:5 use-dilution are:

“Harmful if inhaled. Causes moderate eye irritation. Avoid contact with eyes, skin or clothing. Avoid breathing spray mist. Remove and wash contaminated clothing before reuse. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco.”

The First Aid statements for the 1:5 use-dilution are:

First Aid:

If in eyes:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
- Call a poison control center or doctor for treatment advice.

If inhaled:

- Move the person to fresh air.
- If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible.
- Call a poison control center or doctor for further treatment advice.

If on skin:

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.